



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0026]

Pioneer Hi-Bred International, Inc.; Determination of Nonregulated Status of Maize Genetically Engineered for Herbicide and Insect Resistance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public of our determination that a maize line developed by Pioneer Hi-Bred International Inc., designated as maize event DP-ØØ4114-3, which has been genetically engineered to be resistant to certain lepidopteran and coleopteran pests and to the herbicide glufosinate, is no longer considered a regulated article under our regulations governing the introduction of certain genetically engineered organisms. Our determination is based on our evaluation of data submitted by Pioneer Hi-Bred International, Inc., in its petition for a determination of nonregulated status, our analysis of available scientific data, and comments received from the public in response to our previous notice announcing the availability of the petition for nonregulated status and its associated environmental assessment and plant pest risk assessment. This notice also announces the availability of our written determination and finding of no significant impact.

EFFECTIVE DATE: [Insert date of publication in the Federal Register].

ADDRESSES: Supporting documents, comments we received on our previous notice announcing our preliminary determination, and our responses to those comments may be viewed

at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0026> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue, SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming. Supporting documents are also available on the APHIS Web site at http://www.aphis.usda.gov/biotechnology/petitions/_table_pending.shtml under APHIS petition Number 11-244-01p.

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca Stankiewicz Gabel, Chief, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3927, email: rebecca.l.stankiewicz-gabel@aphis.usda.gov. To obtain copies of the documents referred to in this notice, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Paragraphs (b) and (c) of § 340.6 describe the form that a

petition for a determination of nonregulated status must take and the information that must be included in the petition.

APHIS received a petition (APHIS Petition Number 11-244-01p) from Pioneer Hi-Bred International, Inc., (Pioneer) of Johnston, IA, seeking a determination of nonregulated status for maize (Zea mays) designated as maize event DP-ØØ4114-3 (event 4114), which has been genetically engineered to be resistant to certain lepidopteran pests, including European corn borer (Ostrinia nubilalis), and certain coleopteran pests, including western corn rootworm (Diabrotica virgifera virgifera), as well as to the herbicide glufosinate. The petition stated that this maize is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

In a notice¹ published in the Federal Register on February 27, 2013 (78 FR 13312-13313, Docket No. APHIS-2012-0026), APHIS announced the availability of the Pioneer petition, a plant pest risk assessment (PPRA), and a draft environmental assessment (EA) for public comment. APHIS solicited comments on the petition, whether the subject maize is likely to pose a plant pest risk, the draft EA, and the PPRA for 60 days ending on April 29, 2013.

APHIS received 12 comments during the comment period: Several of these comments included electronic attachments consisting of a consolidated document of identical letters for a total of 573 comments. Issues raised during the comment period include potential effects on human and animal health and non-target organisms, herbicide resistance, corn rootworm resistance, effects of stacked genes, and the length of the comment period. APHIS has addressed

¹ To view the notice, petition, draft EA, the PPRA, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0026>.

the issues raised during the comment period and has provided responses to comments as an attachment to the finding of no significant impact.

National Environmental Policy Act

To provide the public with documentation of APHIS' review and analysis of any potential environmental impacts associated with the determination of nonregulated status of Pioneer's maize event 4114, an EA has been prepared. The EA was prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on our EA, the response to public comments, and other pertinent scientific data, APHIS has reached a finding of no significant impact with regard to the preferred alternative identified in the EA.

Determination

Based on APHIS' analysis of field and laboratory data submitted by Pioneer, references provided in the petition, peer-reviewed publications, information analyzed in the EA, the PPRA, comments provided by the public, and information provided in APHIS' response to those public comments, APHIS has determined that Pioneer's maize event 4114 is unlikely to pose a plant pest risk and therefore is no longer subject to our regulations governing the introduction of certain genetically engineered organisms.

Copies of the signed determination document, as well as copies of the petition, PPRA, EA, finding of no significant impact, and response to comments, are available as indicated in the ADDRESSES and FOR FURTHER INFORMATION CONTACT sections of this notice.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 14th day of June 2013.

Kevin Shea

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2013-14705 Filed 06/19/2013 at 8:45 am; Publication Date: 06/20/2013]